

Clinical trial summary (S2209)

Comparing Drug Combinations for Newly Diagnosed Multiple Myeloma When a Stem Cell Transplant is Not a Medically Suitable Treatment



What is the purpose of this clinical trial?

This study tests treatment for people who are newly diagnosed with multiple myeloma and may not be able to receive a stem cell transplant.

The study will test 2 treatment plans that use a combination of drugs known as DRd. It will compare the 2 DRd treatments to a usual drug treatment known as VRd-Lite.

DRd uses 3 drugs: lenalidomide, dexamethasone, and daratumumab. All 3 drugs have been approved by the Food and Drug Administration (FDA) to treat multiple myeloma.

This trial is set up to find out:

- If DRd treatment lowers the chance that the cancer will spread or get worse
- If DRd treatment helps people with multiple myeloma live longer than the usual treatment
- If DRd treatment improves quality of life for people with multiple myeloma



Why is this trial important?

Stem cell transplant is commonly used to treat multiple myeloma. But due to other health problems or age, some patients may be too frail to receive a stem cell transplant. Doctors want to find better drug treatments for patients who need other options. This trial is a chance to see if DRd treatment can help people live longer and better with multiple myeloma.



Who can be in this trial?

This trial is for adults, age 18 or older, with multiple myeloma.

This trial is for people who:

- Are at increased risk of harmful effects from cancer treatment. Your doctor determines your risk level based on your overall health and age.

This trial is not for people who:

- Have already received treatment for multiple myeloma
- Have severe peripheral neuropathy (a type of nerve problem)
- Have severe heart problems
- Have an active infection of HIV, hepatitis B, or hepatitis C
- Are pregnant














Talk with your doctor to learn more about who can join this study.



What treatments will I get?

Treating multiple myeloma often involves initial treatment and maintenance treatment. Initial treatment is the first treatment you receive for a cancer. You get maintenance treatment after initial treatment to help keep the cancer from coming back.

A computer will randomly assign you to one of 3 study groups.

	Initial Treatment Drugs	Maintenance Treatment Drugs
Group 1 (usual treatment)	VRd-Lite combination of:  Lenalidomide +  Dexamethasone +  Bortezomib	 Lenalidomide
Group 2	DRd combination of:  Lenalidomide +  Dexamethasone +  Daratumumab	 Lenalidomide
Group 3	DRd combination of:  Lenalidomide +  Dexamethasone +  Daratumumab	 Lenalidomide +  Daratumumab



How long will I be in the trial?

You will be in the study for 10 years. Your study doctor will closely watch you for side effects and watch how the cancer responds to the treatment. You will also be asked to fill out short surveys about your quality of life during treatment. You may continue treatment until it stops working or you have side effects that are too severe. You may choose to stop treatment for any reason at any time.

If you stop getting treatment, you will have follow-up visits with the study team until 10 years after you started the study.



Are there costs? Will I get paid?

The study drug daratumumab is provided free to you. You will not be paid for joining the study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study.



Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search using the national clinical trial number: **05561387**



Key information *This trial is for adults 18 years or older being*

Full trial title: A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or in a Subset of "Intermediate Fit" Comparing Upfront Three-drug Induction Regimens Followed by Double- or Single-agent Maintenance.

Protocol number: S2209

NCT number: 05561387

Trial sponsor: SWOG Cancer Research Network

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Thank you!

When you join a clinical trial,
you're moving cancer medicine and patient care forward.